IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:	Robert J. Sicurelli Jr. and Samuel Masyr
SERIAL NO.:	09/990,932
TITLE:	Flexible Post In A Dental Post and Core System
FILED:	November 21, 2001
EXAMINER:	John J. Wilson
MAILING DATE OF ACTION:	August 1, 2007
GROUP ART UNIT	3732

SECTION 132 DECLARATION

I, Robert Sicurelli hereby declare:

I am a specialist in the dental restorative field.

My education and experience is as follows:

In 1981, I received a Bachelor of Arts from New York University at Washington Square. Then in 1985, I became a Doctor of Dental Surgery, receiving my degree from New York University. I further went on to receive the Specialty Certification in Prosthodontics from New York University in 1989. I have taught in Hands-On Clinical courses, such as the Certified Nobel Biocare Lecturer and the Implant Innovations Inc.

Currently, I have a private dental practice, and working as CEO and founder of Tru Flex Post Systems In. For my work I have been awarded the Rensselaer Medal, Fauchardian Predental Honor Society, and the Pierre Fauchard Award for Leadership and Service. Amongst several appointments, I was the United States Delegate to England, International Association of Dental Students and the United States Delegate to Israel, I. A. D. S.

Publicly, I have taught in domestic and international lectures, including Verona, Italy in 1999 and Stockholm, Sweden in 2000. I have lectured

extensively here and abroad on dental posts and their history. I am the Chairman of Continuing Education for Southampton Dental Staff. I have taught a dozen courses, including Veneers and Ceramic Crowns and Flexible Posts- Evolution and Revolution. An example of the research I have conducted and published articles on cross contamination. I am the co-developer and co-inventor of the glass fiber reinforced posts used in dentistry today, and co-developer and co-inventor of nickel titanium irrigation syringes used in dentistry.

I am co-inventor with Dr Samuel Masyr of the subject matter of the above identified patent application.

Prior to my invention of 1993, I was unaware of any use of fiberglass in prefabricated cylindrical endodontic posts.

Metallic endodontic posts are not flexible, so they may inadvertently lead to tooth fractures and root canal failing when a tooth is subject to force from impacts or chewing. Additionally, metallic endodontic posts are subject to weakening from oxidation rusting when exposed to liquids in the mouth. Metal posts as a result of their inability to form anything other than a simple mechanical bond with restorative material or tooth structure can act as a conduit for bacteria down to the canal space.

Non metallic carbon rod posts existed, such as in U.S. Patent no. 5,328,372 of Reynaud and as sold by Bisco, Inc., but carbon rods are inherently less flexible than fiberglass fibers.

For example, according to standard composite material literature, composite materials made of carbon/graphite rods in a resin are stiffer and less flexible than composite materials made of fiberglass fibers in a resin. For example, according to the website of Aerospace Composite Products (acp-composites.com) solid carbon rods

"*are extremely stiff and lightweight and have a very low coefficient of expansion.*"

Furthermore, graphite composites used in making fishing rods can create weak points along the rod. For example, in the website of stcroixrods.com, a special integrated poly curve ™ (IPC) rods eliminates inherent weak points of

fishing rods made of graphite and resins when rolling the graphite. However the IPC rods are considered stronger because

"*stress is distributed along the entire blank. IPC tapers result in superior graphite fiber alignment along the length of the blank. This ensures better longitudinal strength because alignment is never distorted at transition points. It results in more uniform strength, stiffness and sensitivity along the entire blank shaft for vibration transmission and enhanced feel*".

Therefore graphite composite materials have what would be a disadvantage in dental posts subject to longitudinal stress from biting, namely that stress is distributed along its entire length and that it has a stiffness, which is undesirable when flexibility is desired , as in a composite material endodontic post.

In contrast, according to the website of chemposite.com

"*(t)he flexibility of fiberglass is the perfect material for custom shapes and forms.*"

A comparison of fiberglass composite material and graphite composite material made of graphite and epoxy in the website of performancecomposites.com reveals that graphite composite material is five times stiffer than fiberglass composite material. For example, a test of composite materials made of graphite and epoxy has a stiffness of 8×10^6 psi, while a test of fiberglass fibers and resin reveals that the fiberglass composite material has a stiffness of 1.2×10^6 psi. This five fold disparity occurs even though the densities of fiberglass composite material (.055 lb/in^3) and graphite composite material (.065 $lb/in^{3)}$ are relatively similar.

Moreover, a further comparison of E-glass/epoxy unidirectional fiberglass prepreg with AS/3501 carbon/epoxy unidirectional prepreg reveals wide disparities of flexibility vs. stiffness of these two materials in Berenberg; Barry, About Composites/Plastics textbook quoted in the website of composite.about.com .E-Glass/epoxy unidirectional prepreg has a lower longitudinal modulus of elasticity of 5.7 (indicating flexibility) vs. AS/3501

carbon/epoxy unidirectional prepreg having a modulus of elasticity of 20 (indicating stiffness).

Therefore, although stiffer carbon rod manufactured endodontic posts are disclosed in Reynaud, more flexible fiberglass based manufactured endodontic posts were not known until the present invention.

I have reviewed U.S. Patent 4,894,012 of Goldberg. In my experience in dental products, my subject matter describes a non-metallic fiber post in a resin, but U.S. Patent 4,894,012 of Goldberg et al does not.

Goldberg '012 is concerned with custom, patient-specific members such as dentures and bridgework, which span from tooth to tooth, creating a customized prosthesis that can only fit one patient, and which is not a prefabricated cylindrical intra-radicular fiber and resin post, as in Sicurelli '044, which fits all teeth. My device creates a physiological change in the tooth/post relationship by making the unit more flexible than prior art. My device is also bonded within the tooth structure. Goldberg device in contrast creates a stiffer more rigid appliance and is not related at all to a singular intra canal tooth system.

See Charbeneau et al, *Principles and Practices of Operative Dentistry* (1981), pp 446-448 regarding endodontic posts and Tylman, *Crown and Bridge Prosthesis*, Chapter XLII, pp. 871-885, regarding patient-specific dental repair appliances, as distinguishing prefabricated posts from customized patient prostheses.

Based upon my experience in restorative dentistry, a person skilled in that field would not think of using an in situ, spanning fiberglass repair appliance as a source of fiberglass fibers for a non-metallic prefabricated cylindrical post having more flexibility and durability than a non-metallic carbon rod post.

I note in the Office Action of August 1, 2007, that the Examiner notes on pages 2 and 6 thereby that the shape of the post of the subject matter of the present invention is determined by the canal of the tooth. However, the size of the post is determined by the canal. The shape is dependent upon the physical properties required for the post.

Also on pages 3, 6 and 7 of the Office Action the Examiner refers to the "art of implant dentistry." Nothing in your subject matter refers to dental implants. Applicant's subject matter is prefabricated posts for endodontic root canal therapy. An implant is a replacement for a tooth drilled directly into the jaw. Endodontic posts, on the other hand, are inserted into the root canal to support a dental crown prosthesis above the post. Citing dental implants has no place in this discussion.

I note that Independent claims 33, 55, 77, 78 and 101 have been amended to add the following limitations: tooth-force-vectoring as applied to the post being claimed, wherein the described force vectoring comprises dissipation of energy by shifting of stress under excessive tooth force loads, for saving a force-overloaded tooth. The following additional limitations have further been added to the aforesaid independent claims: and further wherein said post has a flexibility approximating the flexibility of a tooth structure; and wherein said post has a modulus of elasticity approximating the modulus of elasticity of a tooth structure.

In regard to the foregoing added claim limitations I respectfully point out that support and antecedent basis for the new claim limitation of tooth-force-vectoring for dissipation of energy by shifting of stress under excessive tooth force loads, for saving a force-overloaded tooth is found in our earlier parent patent application, now U. S. Patent No. 5,518,399 to Sicurelli and Masyr (Sicurelli '399) to the inventors herein, and of which the current application claims priority, at the following places within Sicurelli '399: at column 1 lines 58 - 62; column 2, lines 8-11; column 3 lines 63 - 65; column 4 lines 11-12; column 5 lines 28-31 ("*The flexible, inelastic post reinforcing rod 30 of the present invention also eliminates stress concentrations in the canal wall and dentin due to the apical lateral movement of rigid and elastic posts.*" Sicurelli '399, column 5, lines 28-31). Also, support is found at Sicurelli '399, column 5 lines 61-63 (*"The flexibility of these materials is close to the flexibility of the natural tooth and therefore will reduce the flexibility differential of the intact tooth and the inserted post" Sicurelli '399, column 5 lines 61-63".*)

The foregoing also gives antecedent support and explanation for the newly inserted claim limitation and further wherein said post has a flexibility approximating the flexibility of a tooth structure as clearly pointed out as above-quoted at Sicurelli '399, column 5 lines 61-63.

The portion of the new claim limitations stating wherein said post has a modulus of elasticity approximating the modulus of elasticity of a tooth structure is also pointed out as being essentially the same concept as pointed out as above-quoted at Sicurelli '399, column 5 lines 61-63, but stated with a different descriptive formulation.

The new claim limitation for "force vectoring" simply means that the post of the present invention absorbs a force overload on a tooth where the internal post of the present invention flexes or deforms, as a means of relieving the axial tooth overload due to chewing or trauma.

As for the new claim limitation worded as wherein said post has a modulus of elasticity approximating the modulus of elasticity of a tooth structure is mentioned by Reynaud (5,328,372) at column 1 lines 65-69 and column 2 lines 1-9. Reynaud correctly points out that the modulus of elasticity of an endodontic peg must approximate the modulus of elasticity of a natural tooth, else dire consequences ensue for a tooth later exposed to a force overload.

However, Reynaud '372 announces that his invention provides a modulus of elasticity measured at an average of 21 GPa which Reynaud '372 claims *"... is close to the transverse modulus of elasticity of the dentine (i.e., natural tooth) which is 18."* Reynaud '372, column 2, lines 10-12.

But the *"close"* approximation value of 21 of the modulus of elasticity of the endodontic peg of Reynaud '372 is not actually close enough to the value of 18 GPa, which is that of a natural tooth. The value of the modulus of elasticity of the endodontic post of the present invention should be about that of a natural tooth, i.e., a value of about 18 GPa.

Not only is the value of the modulus of elasticity of the peg of Reynaud '372 too high to be effective for an endodontic post at a value of 21 GPa, but Reynaud '372 also fails to clearly establish how the numerical figure of 21 GPa

was arrived at. At column 2 lines 3-10, Reynaud '372 discusses calculations that are indirect and appear to be an estimate based on an indirect calculation, thus throwing into substantial question the accuracy of the actual value of the modulus of elasticity of the peg of Reynaud '372.

In contrast, the present invention claims a modulus of elasticity approximately that of a natural tooth. Even, arguendo, taking as correct the value of 21 GPa of the modulus of elasticity of the Reynaud '372, the post of Reynaud could not approximate the value of the modulus of elasticity of a natural tooth because it is nearly 17% in excess of the natural tooth dentin modulus of elasticity natural value of 18 GPa. This disparity would cause a substantial disparity in the stress performance of a natural tooth as compared with the peg of Reynaud '372 if implanted therein. This is precisely the stress disparity that Reynaud '372 itself teaches should be avoided.

Also, having a modulus of elasticity in a dental endodontic post less than that of tooth dentin also puts the post at something closer to pulpal tissue and makes the system more physiological matching what was there originally; unlike Reynaud's carbon post and metal posts, both of which have modulus of elasticity which are higher than that of tooth dentin.

The "transverse modulus of elasticity " mentioned in Reynaud also translates into a higher number of modulus of elasticity when measured axially, because it's not calculated using ASTM testing methods, which measure mechanical properties using "vertical pull" on an Instron Company testing measurement apparatus. Transverse modulus incorporates more resin and less fiber into the calculation, than a vertical pull axial measurement noted by Applicants.

I note that the Examiner says that it would be obvious to combine Reynaud's prefabricated post with fiberglass fibers as disclosed in Alpert or Goldberg.

However, one skilled in the art of dental endodontics would not equate the fiberglass fibers of in situ patient-specific installations of Alpert '929 or Goldberg '012 with the present invention. For example, Alpert '929 is a three-step process,

which includes loose, rope-like fibers which are contacted with a stiffening agent and then inserted in the mouth of the patient. Moreover, as noted in Alpert '929 at column 3, lines 62-64, *w(W)hen the rope begins to stiffen, it is shaped by hand or otherwise to fit the contour of the open root canal.*"

The Alpert '929 reference fails to disclose the claimed invention, as recited in the claims now pending in the application. The post of the present invention is claimed as being *prefabricated* and adapted to extend at least from adjacent the coronal end of a tooth canal toward the apical end of that tooth canal. In other words, the endodontic dental reinforcement post of the present invention is insertable, as a complete unit, in a tooth canal. In the Alpert '929 patent there is disclosed a flexible rope-like root canal prosthesis. The cord is inserted into the root canal and is then held in place by the addition of a plastic material, such as a composite resin. This plastic material 34 is shown in Fig. 8 and is clearly separate from the rope-like root canal prosthesis.

In contrast, in my subject matter, the reinforcing rod is placed in the tooth canal that has been sized to receive it. As discussed at Column 7, starting at line 5 of our earlier parent (Sicurelli '399), the reinforcing rod is placed into the root canal, as seen in Fig. 7 or Fig. 8. Those drawing figures shows a tight fit of the reinforcing rods into the tooth canal. Our reinforcing rods are not a thin rope that is inserted into a much larger diameter tooth canal and which is then held in place with a surrounding injection of a separate plastic material 34. Even if Alpert '929 were available as a reference, which it is not because of its subsequent filing date, it could not be combined with the Reynaud '372 reference to arrive at the claimed *prefabricated* endodontic dental reinforcement recited in the claims of the subject application.

The same patient-specific difference between the present invention and that of Alpert '929 is also true when comparing the present invention to that of Goldberg '012, which requires a two-step patient-specific process *"that optimizes the wetting of the fibers, while obviating the presence of voids, thereby enabling the incorporation of significantly higher amounts of fiber with concomitant increases in strength and other desired mechanical properties. Included in this*

object is the provision for the initial production of an effective composite material and the ***subsequent,*** *(emphasis added) formation of the dental component from that material.*" See Goldberg '012 at column 3, lines 55-66.

Moreover, as previously noted in Applicant's Rule 56 Information Disclosure Statement filed under Applicants' earlier parent patent application filed on December 24, 1998 under serial number 08/858,615 , filed May 20, 1997, which was allowed to issue as United States Patent 5,915,970 by Examiner Wilson herein, Goldberg '012 was cited already to the USPTO. The Rule 56 Statement argued that Goldberg's appliance is unique for each individual patient, which is contrary to the subject matter of the present invention which describes a *prefabricated* endodontic post system that essentially fits the canals of all teeth, from out of a box. In that Rule 56 Information Disclosure Statements Applicant also submitted for Examiner Wilson's consideration the PDR (Physician's Desk Reference, as well as the aforementioned dental scholarly publications of Tylman (which described dental appliances, such as in Goldberg '012) and Charbeneau (which defined endodontic posts, such as the subject matter of Applicants herein).

Therefore one skilled in the art of endodontic dentistry would not look to patient specific appliances, as in Goldberg '012, as a source of materials for the non-analogous prefabricated posts of the Applicant's subject matter.

Yet the examiner has here cited Goldberg '012 as rendering the present invention obvious, after allowing a parent application of the present invention to issue as U.S. Patent No. 5,915,970 ('970 Patent of the present inventor).

The Applicant respectfully asserts that if there was insufficient reason to cite Goldberg '012 as a relevant ground of rejection for obviousness at the time of examination of the inventor's '970 issued U.S. Patent, then it is incumbent upon the examiner to point to a substantial new reason to cite the relevance of Goldberg '012 in the case of the present application currently under examination.

In the parent Sicurelli patent, the applicable phrase recites that the *"post reinforcing rod"* is preferably formed from reinforced plastic such as fiberglass polyester composites similar to those used in the construction of fishing poles, flexible ceramic resin composites, graphites, teflons, polycarbonates and the like. Note Column 5, lines 53-57. One reading the description of the fourth embodiment of the post 100, as depicted in Figs. 8 and 9, as including a post reinforcing rod would understand that phrase to be the same, in meaning, as the same phrase used at Column 5, lines 53-57.

It is respectfully submitted that the Examiner's asserted "complete" reading is, in fact, not complete and that his conclusions are not correct. The language of the Sicurelli parent patent, at Column 3, lines 52-67 recited, in their entirety that *"Core spacer 20 and post reinforcing rod 30 are preferably formed from reinforced plastics such as fiberglass polyester composites similar to those used in the construction of fishing poles, flexible ceramic resin composites, graphites, teflons, polycarbonates and the like."* (Emphasis added). The use of a fishing pole is an example of the use of reinforced plastics, such as fiberglass polyester composites, as one kind of a plurality of reinforced plastics that could be used to form the post reinforcing rod 30 or the post reinforcing rod 130.

In Figs. 8 and 9, the post reinforcing rod 130 is formed from a bundle of reinforced plastic or other fibers cemented together. These are the same types of reinforced plastics or other fibers as are recited in connection with Figs. 1-3. These fibers are longitudinally arranged, similar to ones used in the construction of fishing poles. The fibers 101 depicted in Figs. 8 and 9 are also longitudinal strands.

I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such

willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Robert Sicurelli

Dated: October 30, 2007

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited by fax to 571-273-8300 on the date indicated below.

Date: October 30, 2007

Alfred Walker

IN THE UNITED STATES PATENT OFFICE

APPLICANT:	Robert Sicurelli and Samuel Masyr
SERIAL NO.	08/858,615
FILED:	May 20, 1997
FOR:	FLEXIBLE POST IN A DENTAL POST AND CORE SYSTEM
EXAMINER:	C. O'CONNOR
ART UNIT:	3732

RULE 56 INFORMATION DISCLOSURE STATEMENT AND PETITION UNDER 37 CFR 1.97(e)(2)

In order to fulfill the requirements of candor and good faith set forth in 37 CFR 1.56, Applicant submits for consideration by the Examiner this Rule 56 Information Disclosure Statement with the enclosed reference cited on the PTO1499 form. A copy of the foregoing reference is enclosed.

I US Patents

Patent No.	Patentee	Date of Issuance
4,894,012	Goldberg et.al.	Jan. 16, 1990

II Foreign Publications

Country	Publication No.	Publication Date

III Other References

PDR Physicians Desk Reference Medical Dictionary, (1995) p.119, 1412

Charbeneau et al, Principles and Practices of Operative Dentistry (1981) pp. 446-448

Tylman, Crown and Bridge Prosthesis, Chapter XLII, pp 871-835

Applicant submits the Goldberg '012 document for consideration within three months of discovery of same.

The Goldberg patent covers a device with longitudinal fibers in a resin. However, the Goldberg device is an appliance that replaces restores or connects teeth together, such as a denture or set of orthodontic braces. There is no discussion, citation or other mention of the Goldberg device to function as a singular post or post system in endodontically treated teeth. The only mention of the word "post" in the patent of Goldberg is in column 1, line 30 where the Goldberg appliance is said to include "structural components" of a dental appliance.

However, "component" is customarily defined as a constituent part, element, or a part of a mechanical system, the "component" being or serving as an element in something larger.

If it was the intention of the Goldberg device to serve as a singular endodontic post or post system, then the reference would have read "these appliances often includes bars, wires, braces, posts".

Instead, the object of the Goldberg device is to provide an appliance that may incorporate as part or piece of it the elements listed. This mindset is consistent with

all of the cited prior art and literature that describes dentures, bridges, orthodontic appliances, etc. as being for dentures, orthodontic braces, etc., which are custom fit for the particular dental patient.

Accordingly, the Goldberg appliance is formed on a dental cast that is unique for an individual patient. This is contrary to the subject matter of the present invention, which concerns a prefabricated endodontic post system that essentially fits the canals of all teeth out of a box.

In support of this, Applicants submit three publications distinguishing dental appliances from endodontic posts. For example, the PDR, Physician's Desk Reference, clearly distinguishes those two items. Furthermore, while the Charbeneau reference defines endodontic posts, the Tylman reference describes dental appliances, such as braces and dentures.

Pursuant to 37 CFR 1.97, Applicant submits a fee of $220.00 for this document, since a first office action was already mailed on the merits.

Pursuant to 37 CFR 1.97(d) and (e), Applicant submits this document after a final office action, and Applicant certifies under 37 CFR 1.97(e)(2) that the Goldberg `012 patent was not known to Applicant more than three months ago, and was not cited in a corresponding foreign patent application more than three months ago.

The circumstances how the Goldberg `012 patent became known to Applicant less than three months ago are that on

October 26, 1998 Applicant's attorney sent a letter to Jeneric/Pentron Inc. of Wallingford, CT notifying it of Applicants' issued patent nos. 5,741,139 and 5,518,399, both of which are prior parent applications of the above identified patent application under final Office Action.

On October 27, 1998 the general counsel for Jeneric/Pentron, Inc. responded by sending Applicants' attorney the enclosed fax communication with a copy of US patent no. 4,894,012 of Goldberg.

That was the first time Applicants or their attorney became aware of Goldberg `012.

Nor was it cited as a reference by the Examiner in Applicants' prior applications which issued as US patent nos. 5,741,139 and 5,518,399 on May 21, 1996 and April 21, 1998 respectively.

The aforementioned Physicians Desk Reference (PDR), Charbaneau and Tylman are not cited as newly discovered prior art, but rather as evidence in support of Applicants' assertion that the subject matter of Goldberg `012, namely substituent components for patient customized dental appliances such a dentures and orthodontic braces, is quite different from the subject matter of the present application, namely, a prefabicated, generally cylindrical post supporting a crown or tooth in endodontic root canal treatment.

Therefore, Applicant meets the requirements of 37 CFR 1.97(e)(2).

In view of the present submission, it is now believed that the present application is in all respects complete and in condition for examination on the merits.

If the Examiner has an questions or comments relating to the present application, the Examiner is respectfully invited to contact Applicant's attorney at the phone number set forth below.

Respectfully submitted,

Dated: Dec.24, 1998

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pat:56/08858615

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Date: Dec. 24, 1998

Alfred Walker

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Date: October 30, 2007

Alfred Walker